

DES in Thrombosed Coronary Lesions

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Presenting Thrombus Increases PCI Risk

“Why is it important to identify thrombus prior to PCI? Intracoronary thrombus is associated with increased risk of embolization, no-reflow, procedural MI, acute closure, stent thrombosis, etc.”

– Dr. J Carrozza, Jr., TCT 2003

“Thrombus increases procedural risk.”

– Dr. I Moussa, TCT 2004

“Thrombus increases complications.”

– Dr. R Kuntz, TCT 2004

“Thrombotic cases are always an interventional challenge.”

– Dr. G Dangas, Jan 2005, TCTMD

IFU Text for Current DES

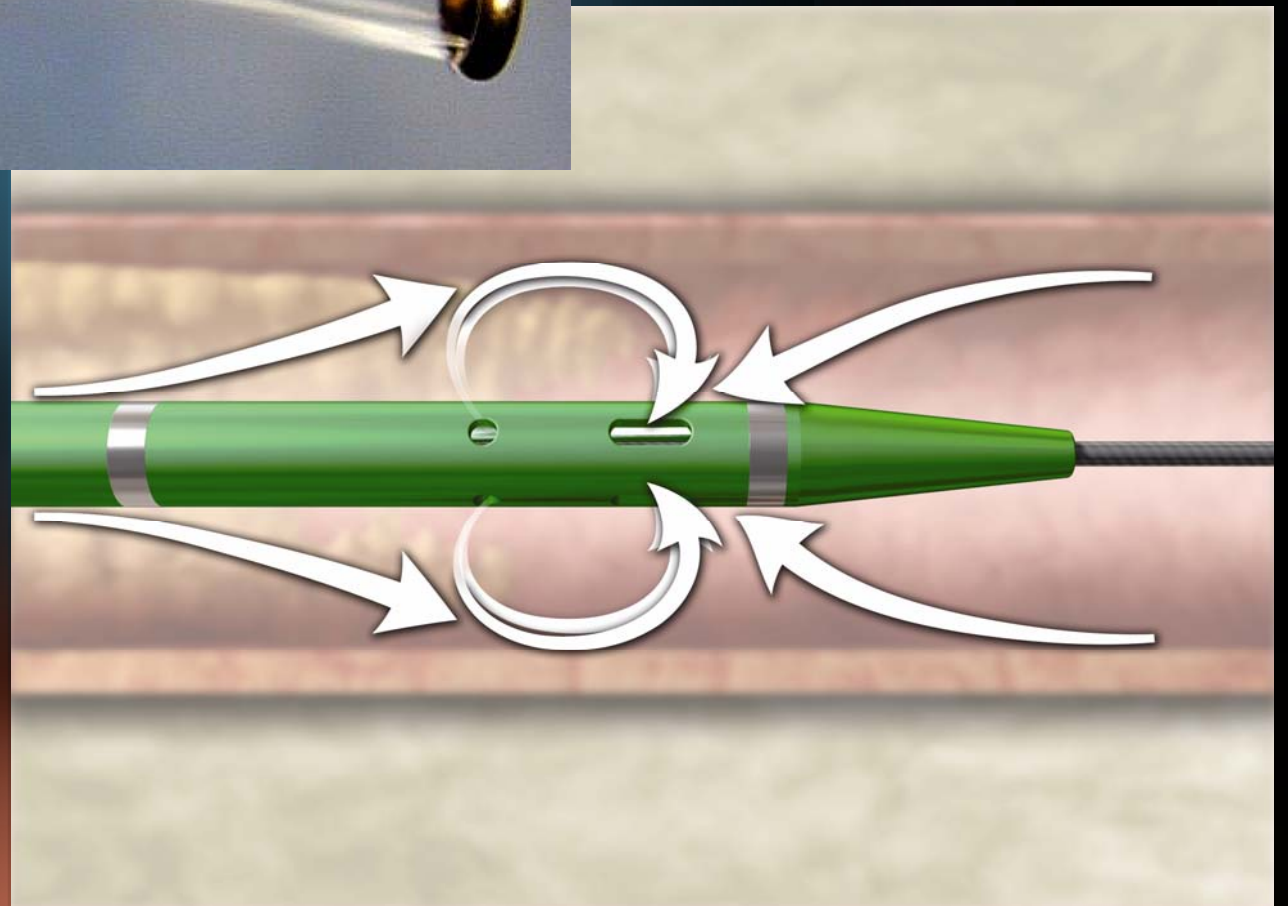
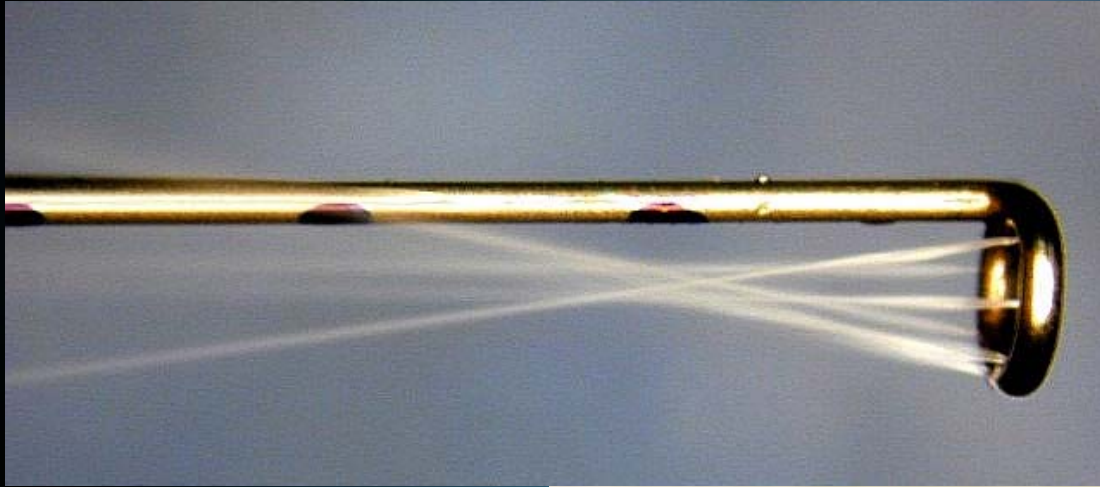
“Safety and effectiveness have not been established in:

1. Patients with unresolved thrombus at the lesion site.”
6. Patients with a recent AMI where there is evidence of thrombus or poor flow.”

AngioJet® Rheolytic™ Thrombectomy System



AngioJet Action



What evidence, including
real-world clinical experience,
characterizes DES outcomes
in these patient subsets?

Pre-Clinical Evidence

"Thrombus Modulates Arterial Drug Distribution for Drug-Eluting Stents."

Hwang CW, Levin AD, Jonas M, Li PH, Edelman ER. Circulation. 2005;111:1619-1626.

Models:

- Computational
- In vitro
- In-vivo

Measurements:

- Drug capacity
- Drug diffusivity
- Convective velocity

Pre-Clinical Evidence

Hwang et. al. conclusions: "Thrombus apposed on stents creates large variations in drug uptake and can act to either increase or decrease wall deposition according to the clot and stent geometry. Arterial deposition of drug from stents deployed in clots will be highly variable and unpredictable unless the clot can be adequately controlled or removed."

Real-World Clinical Experience

“Current Experience and Role of Rheolytic™ Thrombectomy in the Management of Acute Myocardial Infarction with Large Thrombus Burden”.

Journal of Invasive Cardiology.

Vol. 18, Supp C. 2006.

Eds: Drs. Bruce Brodie and Donald Baim

2006 J/C Supplement

Six Independent Clinical Experiences:

- 4 retrospective, 2 prospective.
- 5 single site, 1 multi-site.
- 4 single-arm with concurrent reference sample.
- 1 case-controlled.
- 1 randomized.

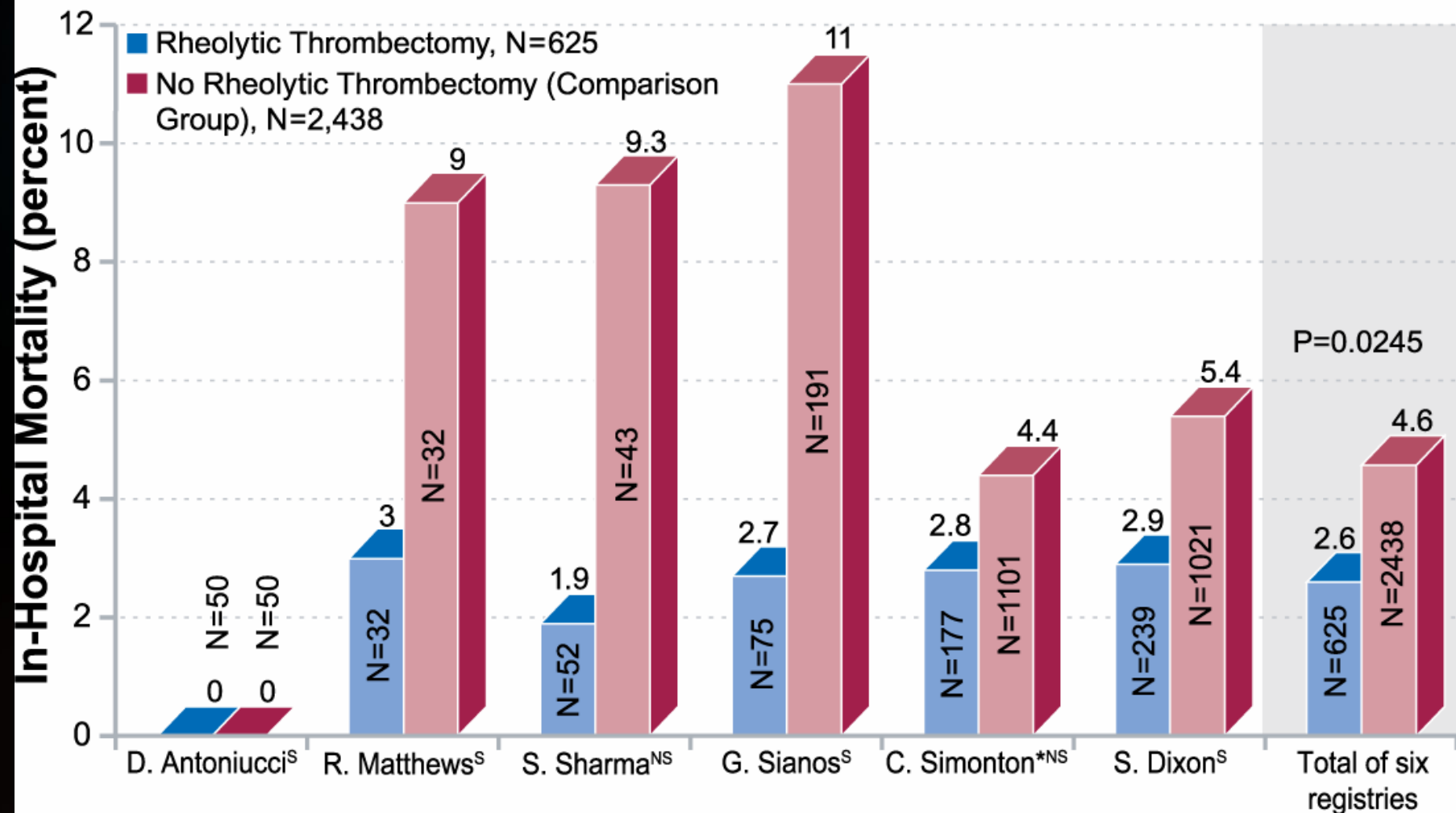
2006 J/C Supplement Patients

	<u>AngioJet</u>	<u>Ref Sample</u>
Patients	625	2,438
STEMI	100%	100%
DES	64%*	71%*
Thrombus	95%*	69%*

*Approximate

2006 *JIC* Supplement Outcomes

Rheolytic Thrombectomy During PCI for AML: In-Hospital Mortality*



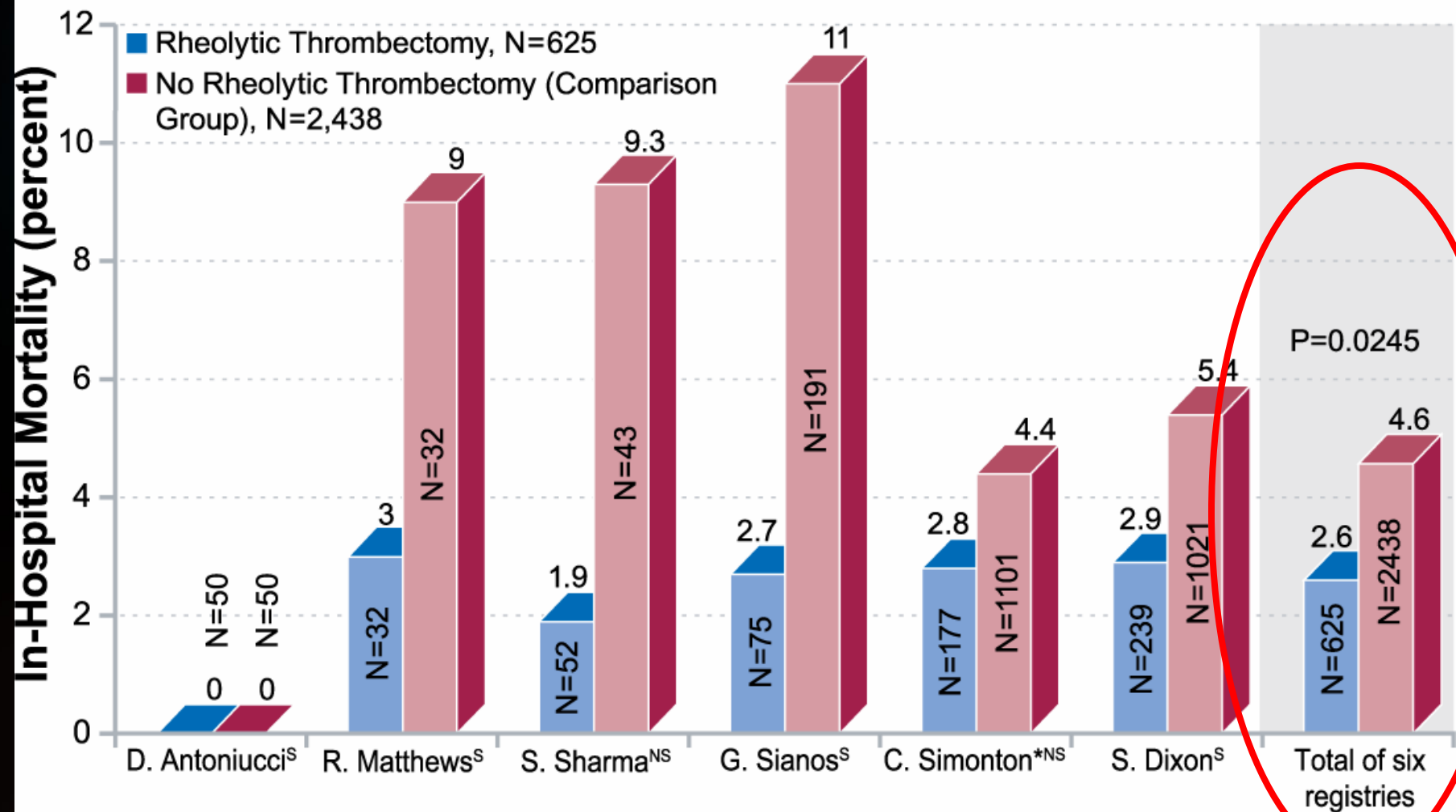
*Nine month mortality for Simonton results.

^S includes cardiogenic shock

^{NS} does not include cardiogenic shock

2006 *JIC* Supplement Outcomes

Rheolytic Thrombectomy During PCI for AML: In-Hospital Mortality*



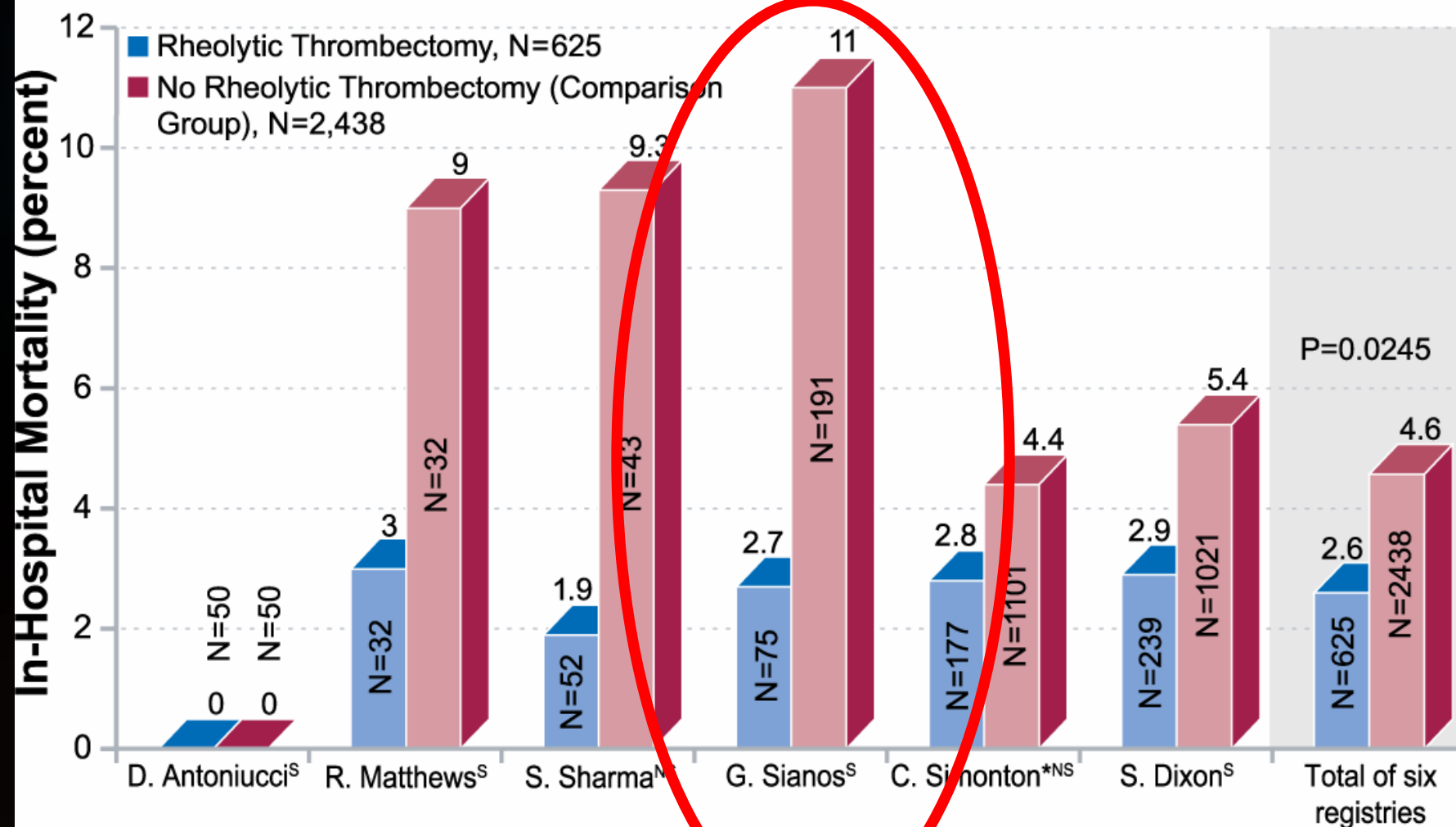
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2006 *JIC* Supplement Detail

Rheolytic Thrombectomy During PCI for AMI: In-Hospital Mortality*



*Nine month mortality for Simonton results.

^S includes cardiogenic shock

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Detail: ThoraxCenter Experience

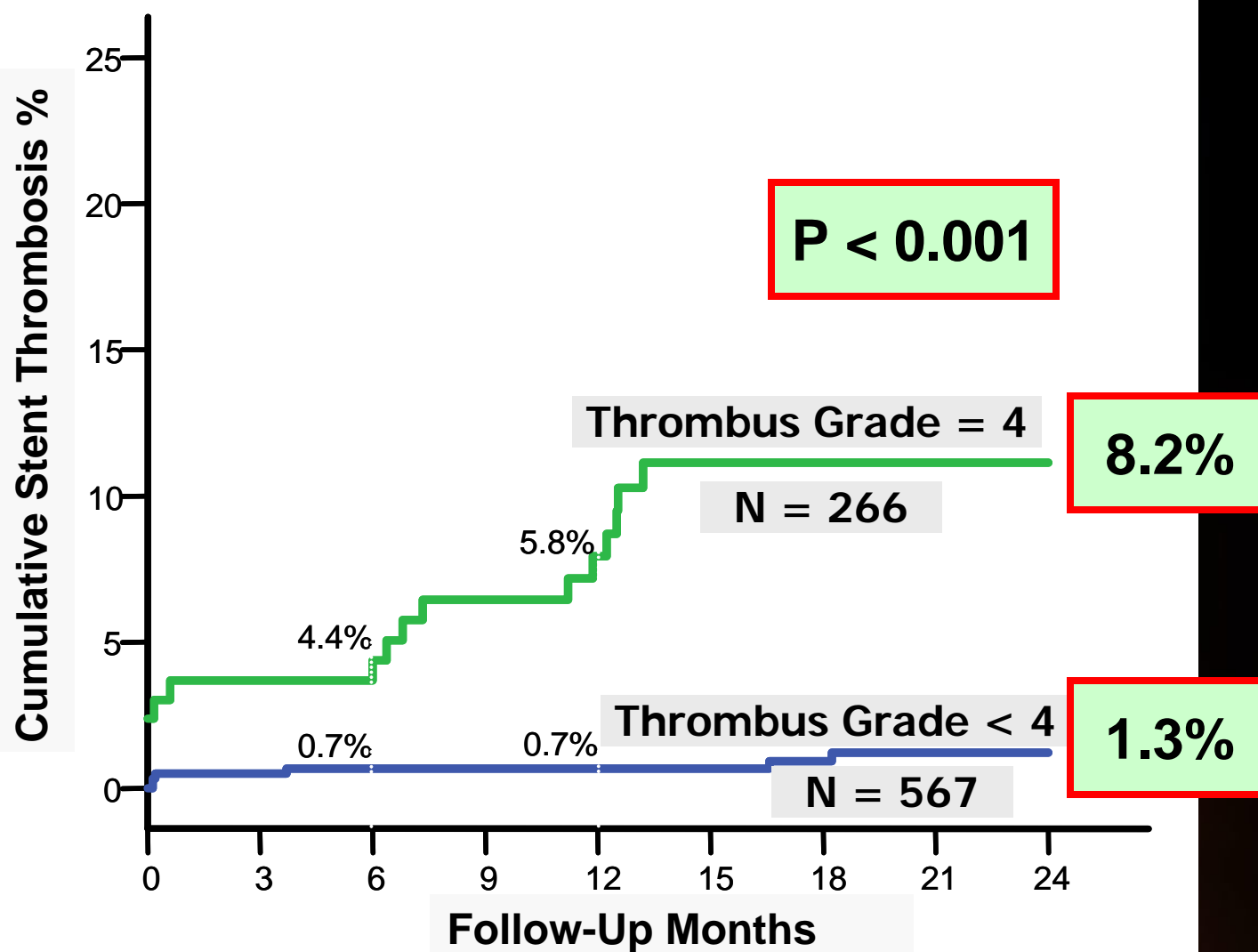
Published/presented by Dr. Sianos:

- JIC Supplement July 2006
- EuroPCR May 2006, Paris
- ESC/WCC Sep 2006, Barcelona
- TCT Oct 2006, Washington DC
- AHA Nov 2006, Chicago

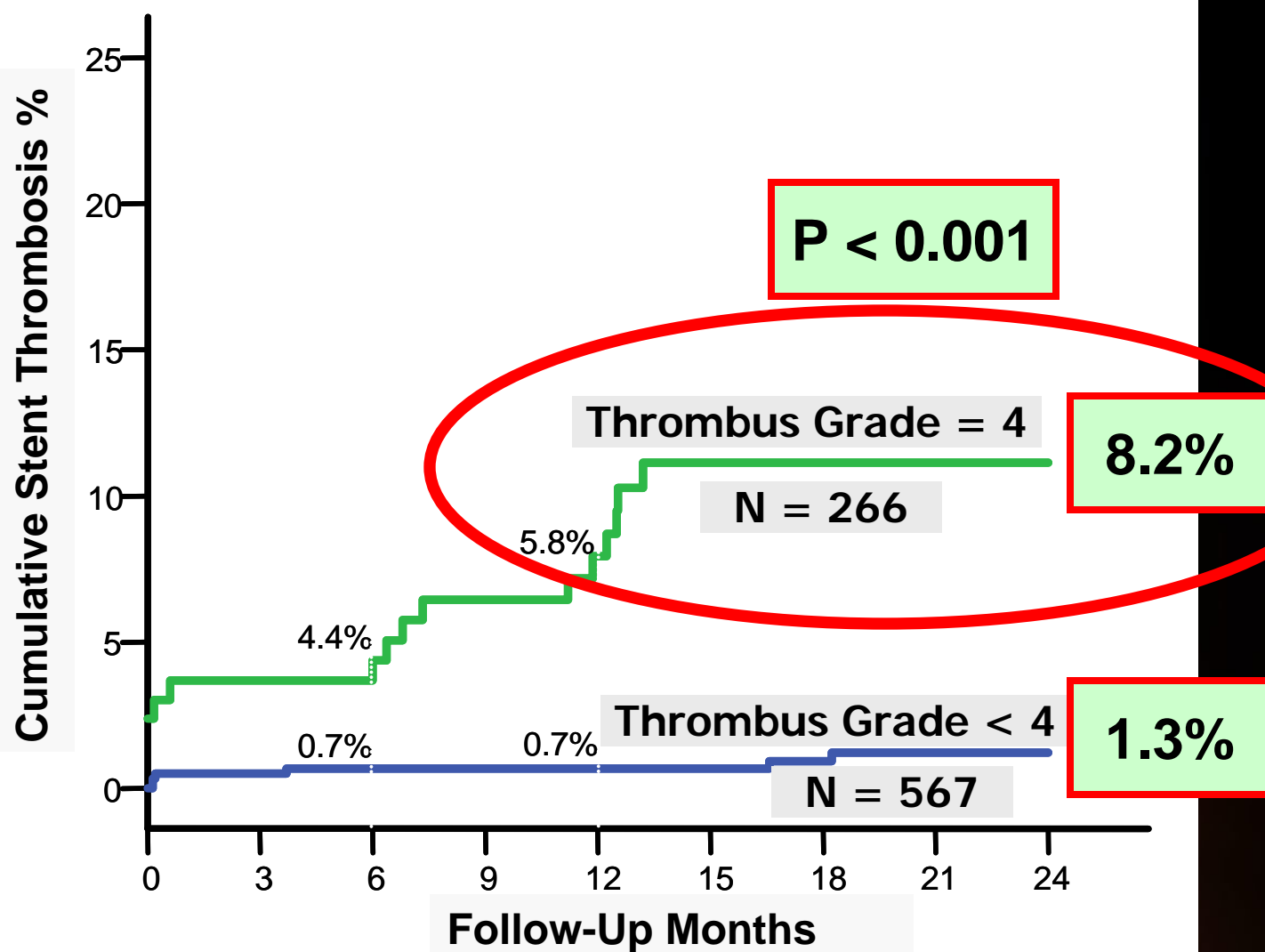
Patients

- 900 sequential pts Apr 02 - Dec 04:
 - STEMI < 12 h.
 - 90.1% received DES
 - DES pts received standard anti-platelet Tx
 - SES: clopidogrel 75 mg/d for 3 m; 325 mg/d ASA indefinitely
 - PES: clopidogrel 75 mg/d for 6 m; 325 mg/d ASA indefinitely
 - Average follow-up of 18 m \pm 8 m.
- 266 (30%) had baseline TIMI thrombus grade 4.
 - 75 AngioJet (only thrombectomy Tx used).
 - 191 direct stenting.

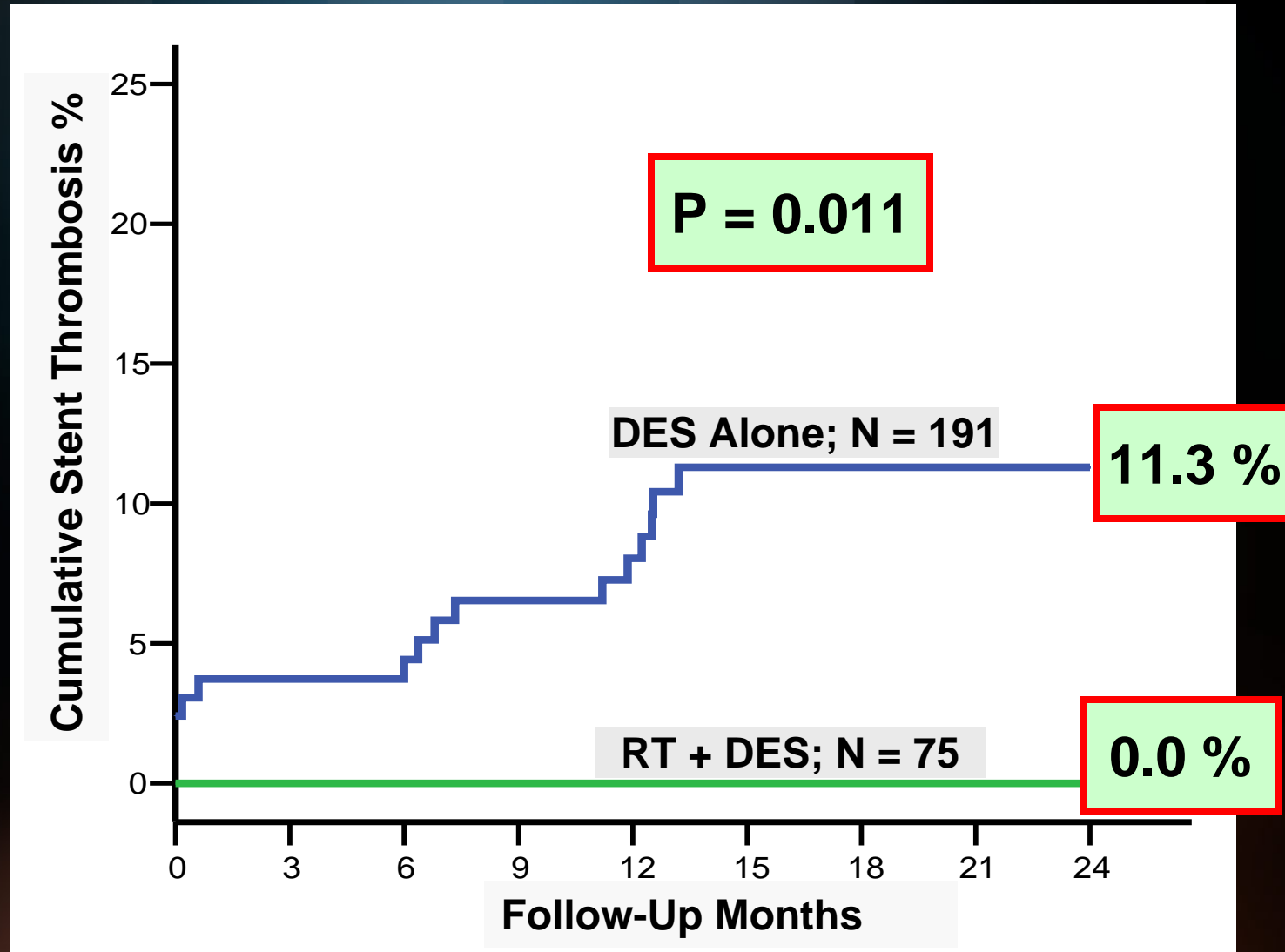
Stent Thrombosis by Thrombus Size



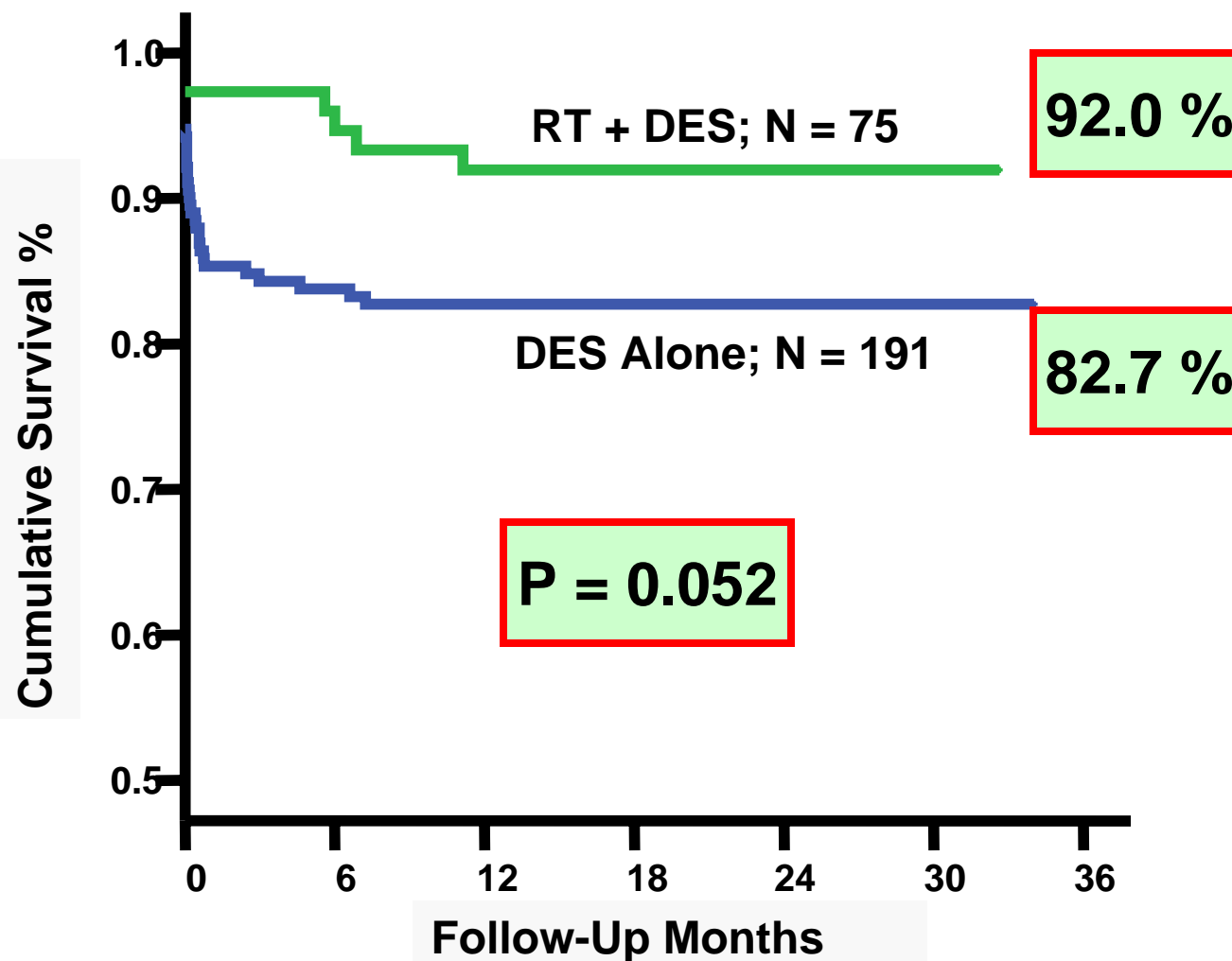
Stent Thrombosis by Thrombus Size



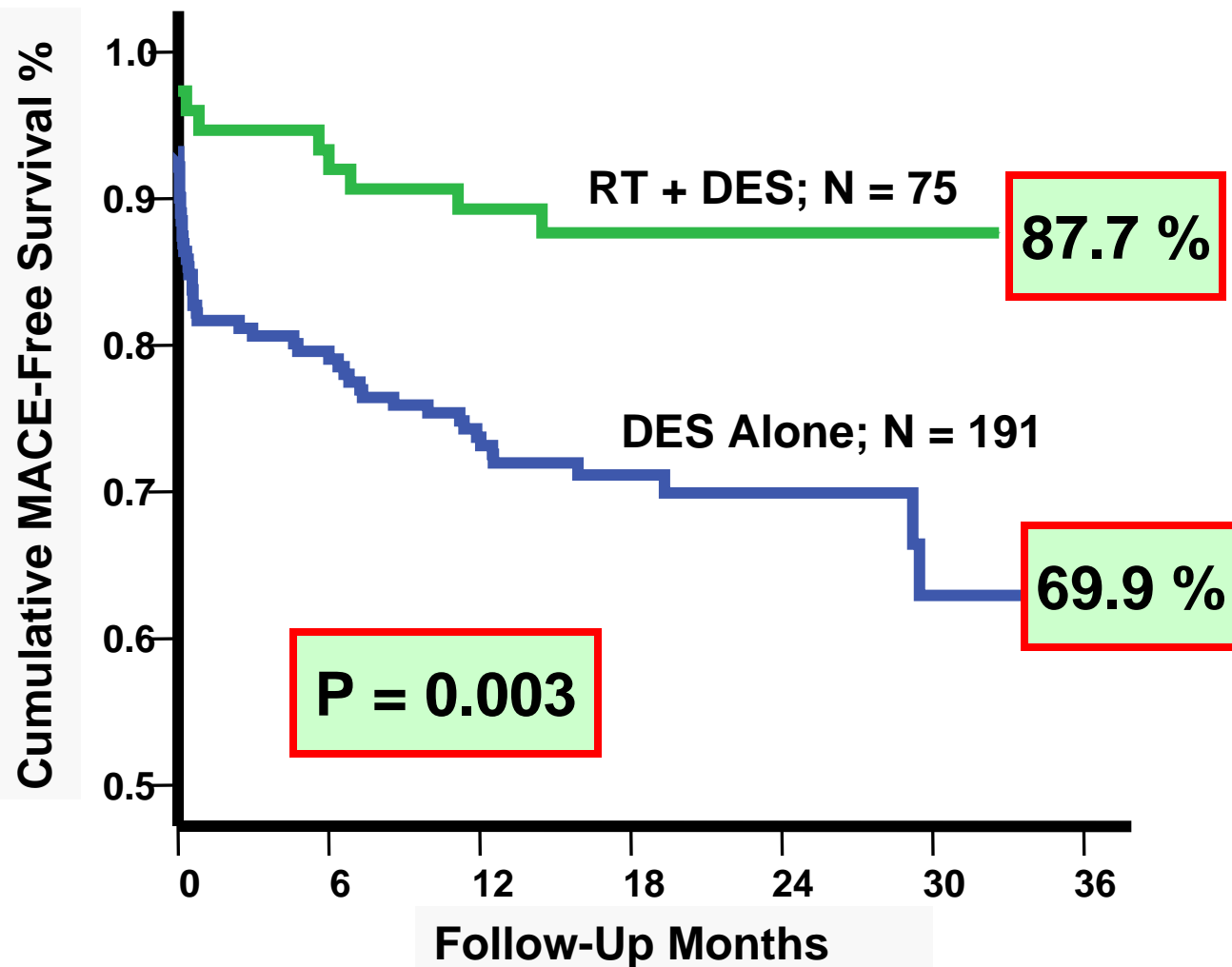
Large Thrombus Patients: Stent Thrombosis



Large Thrombus Patients: Survival



Large Thrombus Patients: Freedom from MACE



ThoraxCentre Experience

CONCLUSIONS:

- In STEMI patients receiving DES, large unresolved thrombus at baseline is a major risk factor for stent thrombosis and a driver for MACE.
- AngioJet thrombectomy before DES in STEMI patients with large presenting thrombus significantly reduces stent thrombosis and MACE.

Overall Summary

- Presenting thrombus complicates PCI.
- Unresolved thrombus negatively affects drug delivery in DES use.
- In STEMI, large thrombus is a risk for higher MACE and stent thrombosis.
- In STEMI patients with large thrombus, AngioJet thrombectomy reduces stent thrombosis from 11.3% to 0.0% ($p=0.011$) out to 2 yrs, and reduces MACE.